

EXHIBIT 11

1 IN THE UNITED STATES DISTRICT COURT

2 FOR THE DISTRICT OF MASSACHUSETTS

3
4
5 THE HIPSAVER COMPANY, INC.,
Plaintiff

6 VS. NO. CV 05 10917 PBS

7 J. T. POSEY,
8 Defendant

9 AND RELATED COUNTERCLAIM.
10
11

12 DEPOSITION of JEFFREY B. BURL, M. D.,
13 taken at the request of the defendant pursuant
14 to Rule 30 of the Federal Rules of Civil
15 Procedure before Nancy A. Diemdowicz,
16 Registered Merit Reporter, a notary public in
17 and for the Commonwealth of Massachusetts, on
18 August 25, 2005, commencing at 7:35 A.M. at
19 the Fallon Clinic, 630 Plantation Street,
20 Worcester, Massachusetts.
21
22
23
24

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2
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15 FOR THE FALLON CLINIC:

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18 One Chestnut Place
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21
22
23
24

1 Q. As I understand the report, it's
2 basically a report of the study, and the
3 purpose of the study was to determine whether
4 residents in long-term health care facilities
5 could be -- I don't want to say convinced, but
6 could be brought to wear hip protectors among
7 people who are at risk for, say, falling and
8 maybe suffering a hip fracture. Is that
9 approximately right?

10 A. That's correct.

11 Q. Okay. In the report, it says that
12 you used a particular brand of hip protector
13 called HipSavers; is that right?

14 A. Correct.

15 Q. What was the reason for picking
16 HipSavers as the product to use among the
17 subjects in the study?

18 A. We had contacted several
19 organizations that were using hip protectors.
20 One organization in Boston, the Pace Program,
21 had been utilizing HipSavers for the past two
22 years.

23 They were very satisfied with the
24 HipSavers' service and delivery and

1 willingness to come out to the facility for
2 instructions on measuring, for example.

3 So we contacted HipSavers, asking
4 them if they'd be willing to provide the same
5 service to us both for the study as well as
6 for, you know, subsequent use, and they
7 agreed.

8 Q. Is it fair to say that HipSaver was
9 not picked as a result of any preference of
10 quality for one brand of hip protector over
11 another?

12 A. The choice of HipSavers was based
13 on the proximity to the study site and their
14 service reputation.

15 Q. Prior to -- have you ever spoken
16 with an individual named Edward Goodwin?

17 A. I had.

18 Q. When's the last time you spoke with
19 him?

20 A. Two years ago.

21 Q. Can you tell from the report what
22 the compliance rate was overall among the --
23 well, let me just withdraw that.

24 The report talks about the results

1 that were reached with respect to 38 residents
2 of the facility that were in the study, right?

3 A. Correct.

4 Q. And from looking at the report, can
5 you tell what the compliance rate was overall
6 for the whole term of this study among these
7 38 residents?

8 A. The 38 residents -- excuse me. The
9 compliance was measured based on daily wear.
10 That was the definition of compliance. And
11 after the first three months, the average
12 daily wear was greater than 90 percent.

13 Q. Do you know how much greater than
14 90 percent it was? My question, really, is,
15 Can we tell from the report what the
16 compliance rate was specifically?

17 A. The compliance rate -- I don't
18 think I -- I don't believe I averaged the
19 compliance rate for the individual, just per
20 month there.

21 Q. Right. And when you say "just per
22 month there," you're pointing to a portion of
23 the chart in the upper right-hand corner on
24 page 247, right?

1 A. Correct.

2 Q. Yeah. And I'm laughing, but I've
3 tried to figure out what each of these numbers
4 is, and I'm not entirely positive and --

5 MR. DAILEY: I move to strike your
6 remark, Mr. Morseburg. You're not testifying.

7 Q. Anyway. So I'm trying to figure
8 out what the compliance rate was.

9 Is there any way you can tell by
10 looking at the chart specifically what the
11 compliance rate was, whether it was 90.1 or
12 whether it was 92, whether it was 93.5?

13 A. By reading the chart here, the
14 chart is a graph depicting the percentage of
15 wear on a daily basis on one axis and
16 individual months on the other axis. And
17 based on the -- on the run graph here, on a
18 monthly basis, the average daily compliance
19 was greater than 90 percent.

20 Q. Okay. You can't tell, for example,
21 whether it was 93 percent --

22 A. We --

23 Q. -- from looking at the chart?

24 MR. DAILEY: Objection.

1 A. I'm not quite sure what you mean.

2 MR. TINGLE: If you don't
3 understand his question, Doctor, he'll
4 rephrase the question for you.

5 A. Okay. I don't understand.

6 Q. You know what? That's a very good
7 admonition I didn't give you. If at any time
8 during the deposition you don't understand a
9 question, just ask me to rephrase it and I
10 certainly will.

11 A. Okay.

12 Q. Yeah. Okay. Let's do it this way.
13 If you look at page 247, below the chart, the
14 first paragraph there, it's not a full
15 paragraph, but the last sentence in that
16 paragraph reads:

17 "By the third month of the
18 study, average compliance exceeded
19 90 percent, and this was sustained
20 for the remainder of the study."

21 And it makes reference to Figure 1.
22 Did I read that correctly?

23 A. Correct.

24 Q. So my -- so, according to the

1 report, the average compliance exceeded 90
2 percent.

3 But my question is, From looking at
4 the chart, can you tell by how much it
5 exceeded 90 percent in any given month or
6 overall?

7 A. Again, maybe I'm not sure I
8 understand your question. But looking at the
9 graph, there's a designation for 90 on the Y
10 axis, and the individual box per month
11 exceed -- above the 90 percentile -- 90
12 percentage.

13 Q. Okay. But let's just do it this
14 way. Looking at eleven one, for example, in
15 the graph, and there's a block in between the
16 90 and the 95.

17 A. Correct.

18 Q. Is there any way to figure out from
19 looking at the chart what that number is? For
20 example, it could be, I don't know, 94.9 or it
21 could be 94.1.

22 Is there any way to tell from
23 looking at the chart?

24 A. To be that accurate, no.

1 Q. Yeah. Okay. Let me just ask this.
2 With the subpoena, I gave you a document
3 request to look for documents to tell what the
4 exact compliance rate was.

5 Did you have a chance to do that,
6 by any chance?

7 A. No, I did not.

8 Q. Okay. Look down at the bottom of
9 the chart -- I'm sorry -- the bottom of
10 page 247, and in the last two sentences of
11 that page, it says:

12 "The average time that hip
13 protectors were worn by the six
14 subjects who died was three months,
15 range zero to seven months. The
16 average compliance was 93 percent,
17 range 67 to 100 percent."

18 Is the statement that the average
19 compliance was 93 percent a reference to the
20 six subjects who died?

21 A. That's correct.

22 Q. Okay. Did anyone from HipSaver
23 ever contact you and ask you whether they
24 could make reference to the results of this

1 per month or approximately 1.5 falls
2 per resident per year. 126 of the
3 falls, 61 percent involved 34 of the
4 38 study participants or one-third of
5 the total 100-bed nursing facility
6 population, average occupancy 98.9.

7 Mean number of falls per
8 participant was 3.9 compared with
9 1.3 falls for those not in the study.
10 There were two hip fractures in the
11 facility in the year before the start
12 of the study. There were no hip
13 fractures in the facility during the
14 13-month intervention," and then it
15 goes on.

16 Was one of the purposes of the
17 study to measure the effectiveness of the hip
18 protectors?

19 A. No.

20 Q. These results that you're reporting
21 here, were these considered important results
22 in the context of the study?

23 And by these results, I'm talking
24 about the falls and the no fractures, or, you

1 know, the two hip fractures in the facility in
2 the year before the study and no hip fractures
3 in the facility during the 13-month
4 intervention.

5 Are those important results in the
6 context of the study?

7 A. I think they were relevant,
8 demonstrating that the individuals that were
9 chosen were those with the highest risk of
10 falls. They had the majority of the falls
11 compared to the other two-thirds that did not.

12 Of interest was that this
13 population that had the majority of falls did
14 not have any hip fractures during the time
15 period.

16 Q. The study -- the report says that
17 there were two hip fractures in the facility
18 in the year before the start of the study.

19 Do you know whether those were hip
20 fractures that were in people who were in the
21 study or people who were outside the study?

22 A. The two hip fractures occurred
23 prior to the start of the study so in the
24 previous calendar year.

1 Q. Correct. And do you know whether
2 they were people who -- they occurred in
3 people who were high risk as opposed to low
4 risk?

5 A. I don't.

6 Q. Is the fact that there were no hip
7 fractures among the residents in the study an
8 important result of the study?

9 A. I think it added relevance to the
10 study that the individuals who sustained the
11 greatest number of falls did not sustain a hip
12 fracture with the use of the hip protector.

13 MR. MORSEBURG: Sorry. Could you
14 read that back?

15 (The record was read by the
16 reporter as requested.)

17 Q. Right. But my question is a little
18 bit different. My question was -- your answer
19 was it provided relevance.

20 But my question was, Was it an
21 important result of the study?

22 A. I'm not sure how you define
23 important. I think it's very subjective. I
24 think it was a very interesting observation

1 that during the period of time that the study
2 was going, we did not have any -- there were
3 no hip fractures in the facility.

4 Q. It was an interesting observation?
5 Was that how you put it?

6 A. That's correct.

7 Q. Yeah. All right. Was that a
8 sig -- was that a significant result of the
9 study, that there were no hip fractures?

10 A. I don't think you could say
11 significant. The number of fractures
12 previously and the number of individuals
13 tested could not give you any statistical
14 significance whether the HipSavers made the
15 difference but --

16 Q. And that's my point.

17 A. Right.

18 Q. There's nothing to say that the
19 people that were wearing -- and I don't want
20 to say one brand or another -- but the fact
21 that the people were wearing the hip
22 protectors didn't suffer any fractures, I
23 mean, there's no way you can draw a
24 cause-and-effect relationship, is there?

1 A. Statistically, that's correct.

2 Q. If you'd look at page 247 in the
3 report, in the second column, the middle
4 paragraph at the end, the last two sentences,
5 it says:

6 "Two participants wore hip
7 protectors regularly for the first
8 month of the study but reported
9 that they were not comfortable.
10 Despite size changes, these subjects
11 elected not to continue the hip
12 protectors, but were counted in the
13 compliance data."

14 Is it fair to say that two of the
15 38 participants withdrew from the study after
16 the first month? Is that how I read that?

17 A. That's correct.

18 Q. Okay.

19 A. Withdrew their consent to wear the
20 pads.

21 Q. Okay. In the study, you cite a lot
22 of other literature in the area, and if you
23 could take a look at page 249 -- pages 249
24 through 250, if I wanted to get ahold of

EXHIBIT 12

EXHIBIT 12

SUBJECT TO PROTECTIVE ORDER

ATTORNEYS' EYES ONLY

FILED UNDER SEAL

EXHIBIT 13

EXHIBIT 13

SUBJECT TO PROTECTIVE ORDER

ATTORNEYS' EYES ONLY

FILED UNDER SEAL

EXHIBIT 14



HOME

HIPSAVER MODELS

VALIDATION & TESTING

INDUSTRY COMPARISONS

HIP PROTECTORS & THE LAUNDRY

TESTIMONIALS

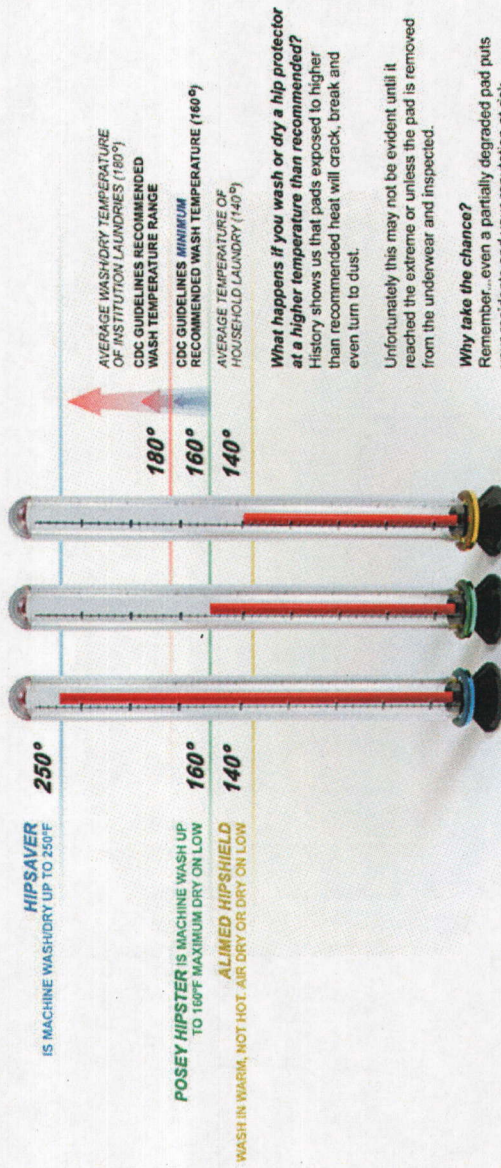
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HIP PROTECTORS & THE LAUNDRY

Only HipSaver hip protectors clearly meets the CDC Guidelines for infection control in the laundry



Compare:

HipSavers® wash and dry up to 250° — well above the CDC guidelines.

Posey® Hipsters wash care instructions: Up to a **maximum** of 160°F (CDC guideline suggested **minimum**) Dry on low.

Alimed® HipShield wash in warm, not hot water and either air dry or dry on low.

ALIMED HIPSHIELD
MACHINE WASH DRY LOW TEMP

POSEY HIPSTER
MACHINE WASH DRY UP TO 160°F

HIPSAVER
MACHINE WASH DRY UP TO 250°F

Only HipSaver can be laundered according to the CDC (Center for Disease Control) Guidelines for laundry.

And the track records prove it. HipSaver hip protectors won't fall apart or degrade like our competitors —we guarantee it!

Click here to view the [CDC Guidelines for Laundry in Health Care Facilities](http://www.hipsaver.com/thelaundry.html).

EXHIBIT 15

Guidelines for Laundry in Health Care Facilities

Introduction

Although soiled linen has been identified as a source of large numbers of pathogenic microorganisms, the risk of actual disease transmission appears negligible. Rather than rigid rules and regulation, hygienic and common-sense storage and processing of clean and soiled linen are recommended. Guidelines for laundry construction and operation for health care facilities have been published (1,2).

Control Measures

Soiled linen can be transported in the hospital by cart or chute. Bagging linen is indicated if chutes are used, since improperly designed chutes can be a means of spreading microorganisms throughout the hospital (3). Recommendations for handling soiled linen from patients on isolation precautions have been published (4).

Soiled linen may or may not be sorted in the laundry before being loaded into washer/extractor units. Sorting before washing protects both machinery and linen from the effects of objects in the linen and reduces the potential for recontamination of clean linen that sorting after washing requires. Sorting after washing minimizes the direct exposure of laundry personnel to infective material in the soiled linen and reduces airborne microbial contamination in the laundry (5). Protective apparel and appropriate ventilation (2) can minimize these exposures.

The microbicidal action of the normal laundering process is affected by several physical and chemical factors (5). Although dilution is not a microbicidal mechanism, it is responsible for the removal of significant quantities of microorganisms. Soaps or detergents loosen soil and also have some microbicidal properties. Hot water provides an effective means of destroying microorganisms, and a temperature of at least 71 C (160 F) for a minimum of 25 minutes is commonly recommended for hot-water washing. Chlorine bleach provides an extra margin of safety. A total available chlorine residual of 50-150ppm is usually achieved during the bleach cycle. The last action performed during the washing process is the addition of a mild acid to neutralize any alkalinity in the water supply, soap, or detergent. The rapid shift in Ph from approximately 12 to 5 also may tend to inactivate some microorganisms.

Recent studies have shown that a satisfactory reduction of microbial contamination can be achieved at lower water temperatures of 22-50 C when the cycling of the washer, the wash formula, and the amount of chlorine bleach are carefully monitored and controlled (6,7). Instead of the microbicidal action of hot water, low-temperature laundry cycles rely heavily on the presence of bleach to reduce levels of microbial contamination.

Regardless of whether hot or cold water is used for washing, the temperatures reached in drying and especially during ironing provide additional significant microbicidal action.

Recommendations

1. Routine Handling of Soiled Linen

- Soiled linen should be handled as little as possible and with minimum agitation to prevent gross microbial contamination of the air and of persons handling the linen. *Category II*
- All soiled linen should be bagged or put into carts at the location where it was used; it should not be sorted or pre-rinsed in patient-care areas. *Category II*
- Linen soiled with blood or body fluids should be deposited and transported in bags that prevent leakage. *Category II*
- If laundry chutes are used, linen should be bagged, and chutes should be properly designed. *Category II*

2. Hot-Water Washing

If hot water is used, linen should be washed with a detergent in water at least 71 C (160 F) for 25 minutes. *Category II*

3. Low-Temperature Water Washing

If low temperature (<70 C) laundry cycles are used, chemicals suitable for low-temperature washing at proper use concentration should be used. *Category II*

4. Transportation of Clean Linen

Clean linen should be transported and stored by methods that will ensure its cleanliness. *Category II*

References

- U.S. Department of Health and Human Services. Guidelines for construction and equipment of hospital and medical facilities. Washington: Government Printing Office, July 1984. DHHS publication No. (HRS- M-HF) 84-1.
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- Christian RR, Manchester JT, Mellor MT. Bacteriological quality of fabrics washed at lower- than-standard temperatures in a hospital laundry facility. Appl Env Microbiol 1983;45:591-7.

7. Blaser MJ, Smith PF, Cody HJ, Wang WL, LaForce FM. Killing of fabric-associated bacteria in hospital laundry by low temperature washing. J Infect Dis 1984;149:48-57.

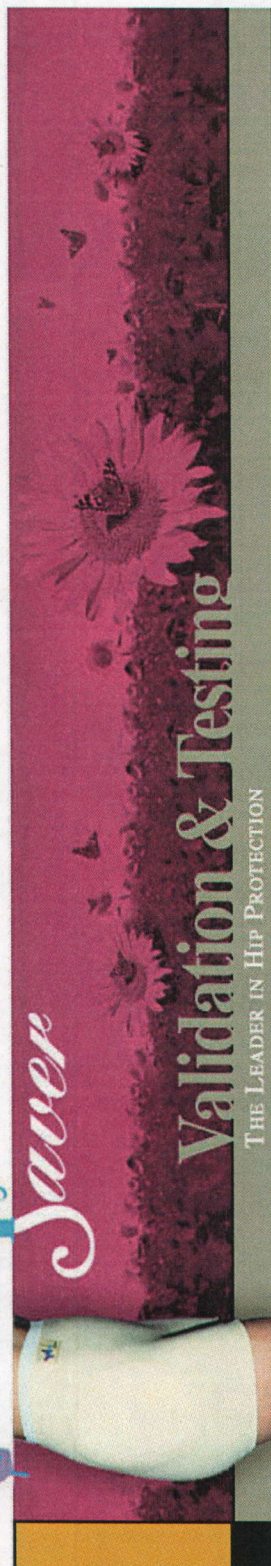
Reference: Guideline for Handwashing and Hospital Environmental Control, 1985; Garner, J.S., Favero, M.S., in Guidelines for Protecting the Safety and Health of Health Care Workers

Office of Health and Safety, Centers for Disease Control and Prevention,
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Last Modified: 02/05/02



 [Send us your Comments.](#)

EXHIBIT 16



Validation & Testing

THE LEADER IN HIP PROTECTION

HOME

HIPSAVER MODELS

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New published study reports high compliance rates and no hip fractures with HipSaver.

The results of a 13 month long study were published in the Sept/Oct. 2003 issue of the Journal of the American Medical Directors Association. HipSavers were written into the care plan of 38 at-risk residents. The study authors report an average 93% compliance rate for the duration of the study. Equally important, there were 126 falls among the HipSaver wearers and no hip fractures. The results are very significant since compliance is a major ingredient in the success of any hip protector program. Previous studies on hard-shell hip protectors have reported much lower compliance rates.

The HipSaver study is available from the publication (*J Am Med Dir Assoc* 2003; 4: 245-250) or on-line at www.iamda.com.

Results: Average compliance as per care plan: 93%
Number of falls in HipSaver wearer group: 126
Number of hip fractures in HipSaver wearer group: 0



[Click here to see abstract of this published study:](#)

Clinical study published in October 2000

The *Elder Service Plan of the East Boston Neighborhood Health Center* conducted a study to investigate the efficacy of HipSavers.

In this controlled study, the group wearing HipSaver hip protector underwear had a 0% fracture rate (199 falls over 26 months) compared to a 4.3% fracture rate (369 falls over 26 months) for the less at-risk control group. Today, after more than four years and over 400 falls, there still has not been a single fracture among HipSaver wearers.



Click here to see this study, published in *Advance for Physical Therapists* (Vol.11, Number 22, pp 45-46) October 30, 2000 (PDF).

Biomechanical Testing

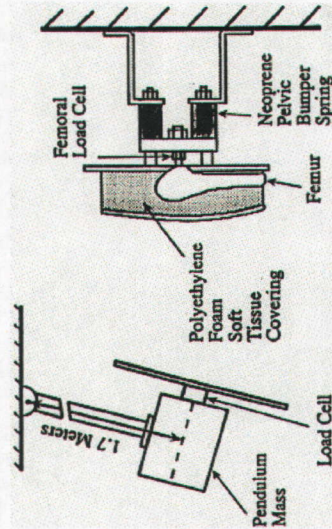
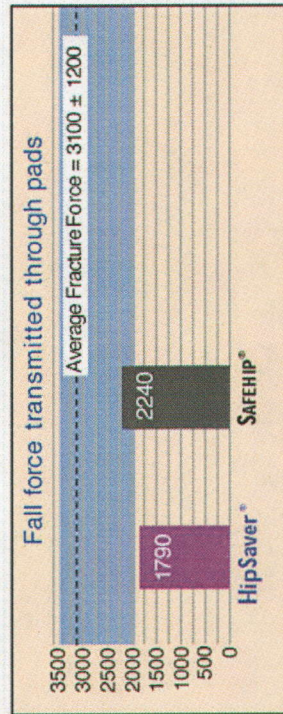


Illustration of Biomechanical Testing Apparatus at Harvard University

HipSaver has been independently tested at two prestigious Universities: A mechanical pelvis was used to record pad protective effect in a simulated fall condition of an elderly person. These tests, conducted at Harvard University and Tampere University of Technology in Finland, two of the leading researchers of hip protection, relate the protective effect of pads to the literature-established bone fragility of an elder person's trochanter.



Results show the HipSaver airPad™ technology reduced the force of impact from 7300 Newtons to 1790 Newtons – that's more than 20% more force reduction than the hard-shell protection.

(Average fracture force: $3100 \text{ N} \pm 1200 \text{ N}$)



Click here to view Biomechanical Test Documentation published in *Bone* (August 25, 1999, (2):229-235) and HipSaver test report from *Tampere University of Technology*, Finland, Sept. 15, 2000.

In order to view certain documents, the latest Adobe Acrobat Reader will be required. Simply click on the "Get Acrobat Reader" icon below to download this free software.



Call or email for your complimentary DVD or VHS video program entitled **"Protecting people from the effects of falling"**. It is offered to healthcare professionals, social services executives, home care staff and other professionals involved with Falls Prevention Initiatives or practically interested in the prevention of fall related injuries. The program was produced in the UK and features Dr Tahir Masud of Nottingham City Hospital; Dr Bernard Walsh from St. James's Hospital in Dublin; Mr George Gross from Boston, MA and others.

PRODUCT VALIDATION & TESTING

HipSaver was introduced in 1994 by Ed Goodwin, consumer products engineer trained to develop effective consumer-friendly products. This training is evident in HipSaver products.

Since 1994, tens of thousands of HipSavers have been sold to nursing homes, elder communities and individual active seniors. HipSaver is fast becoming the preferred choice of VA Long term care units, nursing homes and structured Elder Service Plans such as PACE Communities, around the country and around the world.

Early investigators proposed hard "shunting" shells as the preferred hip protector means but recent independent university biomechanical tests conclude that the HipSaver airPad™ can be more effective in shock force reduction than the hard shell. The HipSaver hip protector therefore offers better protection without the discomfort of hard shell protectors.

HipSaver® – the only proven, all-soft hip protector.

Why is this important to you?

Independent biomechanical testing and clinical validation are crucial for a hip protector. Without them, you won't know IF it works until it HAS to work. And that is too late.

Think of it this way...which parachute would you choose?

One manufactured by a company with proven testing, independent scientific validation and years of market success or one that looks similar but has no performance data or market history.

Don't Settle for Less...

Insist on original, independently validated HipSaver!

It takes more than foam pads and underwear to provide all-soft hip protection that works! Beware of imitators seeking to cash in on years of HipSaver research, development and testing in materials, processes and actual use.

Only HipSaver products have the unique patent-pending dual-mechanism shunting/absorbing HipSaver® airPad™ – a system shown to deliver significant impact reduction in independent testing.

In the event of a fall, the HipSaver airPad absorbs impact and inflates the pouch. Acting as a miniature automobile air bag, it shunts force away from the vulnerable hipbone to the soft tissue of the buttocks.

HipSavers are the only all-soft hip protectors, proven effective – in both independent biomechanical testing and clinical study.

HipSaver® – the only proven, all-soft hip protector.

Email us at hipsavers@msn.com or call HipSaver toll-free at 1-800-358-4477 for answers to your questions or to discuss any issues.

While HipSaver has achieved excellent and impressive results, no product can claim to be 100% effective all of the time. Therefore HipSaver, Inc. makes no implied or express guarantee that its product will prevent injury.

— TOP OF PAGE —

EXHIBIT 17

Published in *Advance for Physical Therapists* October 30, 2000, Volume 11, Number 22, pp 45 – 46

HIP PADS: EFFECTIVE FRACTURE PREVENTION

Simple intervention can reduce the risk of falls resulting in hip fracture

By George Gross, PT, Tsan-Hui Chen, OTR/L, Carolyn Flaherty

Falls are a serious problem in the elderly. One of the most significant consequences of falls is hip fracture, caused by the sudden transmission of a large, mechanical load, which damages tissues and cells. If this energy load could be dissipated over a larger area, injury could be prevented. This review examines the results of a program that used hip pads in community dwelling, frail elders and found impressive results in hip fracture prevention. There was a hip fracture rate of 0 in the study population compared to a rate of 4.3 $P=0.00089576$ and a highly significant difference.

This study examines the results of a program at the Elder Service Plan of East Boston that used HipSavers for patients with histories of frequent falls to absorb and dissipate the energy transmitted in a fall to prevent hip fractures. HipSavers are underpants with soft thin pads of laminated, shock absorbing elastomers covering each trochanter.

Fall Statistics

Falls are a major health hazard in the elderly. One-third of all elders older than 65 years of age fall at least once a year.^{1 2 3 4} Loss of independence often follows a fall. Falls are a factor in 40 percent of nursing home admissions.⁵ The more frequently falls occur, the greater the likelihood of mortality and morbidity for the older adult.⁶ Fall related injuries are the leading cause of death from injury in people over 65.^{1 7} Only 50 percent of individuals admitted to hospitals as a result of a fall will be alive in one year.^{3 8}

Ten percent of falls in the elderly result in serious injury and 5 percent result in some type of fracture.^{4 8} The rate of hip fracture as a result of falls in the elderly has been calculated between 1 percent and 2.9 percent.^{2 7 9} Hip fractures are one of the most catastrophic, life changing and life threatening consequences of falls and frequently result in decreased mobility and loss of independence in older adults.³ Hip fracture is the most common among all injuries leading to hospital admissions in the United States¹⁰ and is a contributing factor in 40 percent of admissions to nursing homes.^{3 11} One-quarter of these patients die within six months of injury and of those remaining alive, 60 percent have decreased functional mobility and 25 percent remain functionally dependent after a hip fracture.¹²

Rehabilitation after a hip fracture is expensive in emotional and social as well as financial costs. The Center for Disease Control and Prevention statistics for 1994 report 243,000 hip fractures per year. The cost of caring for older patients with hip fractures is \$2 billion annually.¹⁰ Falls pose a particular problem for public health professionals in the development of both surveillance systems and prevention strategies.⁷ Most falls do not result in serious injury and are therefore not reported. The absence of injury probably accounts for the poor reporting of falls and underestimation of the problem.¹⁰ Adler-Trainee views injuries as predictable events that have remedial behavioral and environmental antecedents.⁵ Therefore, they can be reduced in number and severity by proper interventions.

Prevention Strategies

Effective fracture prevention strategies can be cost effective and beneficent interventions. Identifying patients at risk permits interventions aimed at reducing both intrinsic and extrinsic risk factors for falls and fractures. Falls are multifactorial. The primary goal is treatment of the problem or the cause to effect clinical change. If change is not expected, the course of action is compensation. For certain patients, the risk of falling remains great despite preventive measures. For these patients, the use of padded undergarments to absorb the impact of a fall and thereby reduce the risk of a hip fracture from a fall has been advocated. Sattin⁷ views injury as a disease with a short latency period. In a fall, a large mechanical energy load is quickly transmitted and damages cells and tissues, potentially resulting in a hip fracture. If the same energy load could be transmitted at a slower velocity or dissipated over a larger area, injury could be prevented.

Study

Subjects. The Elder Service Plan is a full-service health care program for frail elders who meet Massachusetts state requirements for nursing home care but desire to remain at home. The mean age of members is 80 years. Members require some assistance with personal care and activities of daily living (ADLs) and have some combination of acute/chronic medical conditions that requires professional monitoring or supervision. The average number of medical conditions is 9.9/member.

Members who were assessed at high risk for falls because they had two or more falls in the previous four months were evaluated for wearing padded underwear to reduce the risk of hip fracture from a fall. This was a non-random assignment of groups but was undertaken in an attempt to immediately reduce the risk of injury in the high fall risk population. Twenty-nine members wore HipSavers during the study and 438 members did not. The two groups were similar along age and sex dimensions. The mean age of the HipSaver population was 79, one year younger than the control population and there were 6 percent more males in the non HipSaver population. The HipSaver population had much higher percentages on measures of history of falls and history of prior hip fractures.

Not all 29 test subjects wore HipSavers for the entire 26-month study period. Some developed an increased risk for falls later in the test period and were prescribed HipSavers and their subsequent falls were included in the study group data. Members and/or their family/guardian consented to the use of HipSavers as an injury risk reduction intervention.

Method. Falls were recorded on incident report forms. Falls were defined as events resulting in a person inadvertently coming to rest on the ground. Not all falls that occur at home are reported but underreporting skews the data toward serious falls since falls with subsequent consequences are more likely to be reported than falls without injury. Members with a history of falls or high risk factors were evaluated for HipSavers. Incidence of hip fracture in the member population and the HipSaver population were calculated and compared using Fisher's exact test.

Results. The total falls reported were 568 in the 467 members studied over the 26-month period. The 29 members who wore HipSavers accounted for 199 falls or 3.17 falls/member/year. The 438 members who did not wear HipSavers had 369 falls or 0.3888 falls/member/year indicating that the HipSaver group was at nearly eight times higher risk for falls.

Sixteen of the 369 falls among the members not wearing HipSavers resulted in a hip fracture. None of the 199 falls among the members wearing HipSavers resulted in hip fracture. Fisher's exact test analysis comparing falls between the HipSaver and non-HipSaver populations yields a probability of 0.00089576 that this distribution is random. This is less than 0.05 and therefore a highly significant difference.

Discussion. Hip fractures in the elderly are devastating, costly, traumatic, life altering and life threatening events. Most hip fractures occur as a result of falls. This has logically led to strategies of risk reduction through fall prevention. "Falls don't just happen. They are predictable occurrences, the outcome of a multitude of host related and environmental factors that are potentially amenable to intervention and thereby reduction or prevention."¹¹

Despite fall prevention efforts, some patients still experience falls and therefore remain at risk for hip fracture. For some of these patients, HipSavers are an effective injury prevention intervention. This study indicates that shock absorbing hip pads effectively reduced the risk of hip fracture in this Elder Service Plan population. Comparing the cohort of clients wearing HipSavers to those not wearing HipSavers indicates that the experimental group clients are less likely to incur a hip fracture as a result of a fall.

The sample size is small but the results were significant for the Elder Service Plan in implementing a simple, cost effective intervention to reduce hip fractures. The subjects were not randomly assigned but were selected from the same population and prescribed hip pads because of their history and risk of falls. They fell nearly eight times more frequently than the members of the control population. This would seem to make them more likely to sustain a hip fracture but in fact, no hip fractures were sustained by this group, a very promising finding. This study did not include measures of osteoporosis, bone density, nutrition or endocrine factors, which may cause potential differences between the groups likelihood for fracture and this is an area for further study.

Conclusion

Much research has been done on the costs and consequences of hip fractures and the causes of falls. Fall prevention programs are a necessity for any geriatric program. Despite all fall prevention efforts, some elders continue to fall. Compensatory strategies aimed at reducing the risk of injury from falls is the logical course of action. HipSavers are an effective means of reducing the risk of hip fracture from falls in this population. Despite their effectiveness, HipSavers are not for everyone. Some clients dislike their bulky appearance and choose not to wear them. Some clients, especially those who struggle with ADL's, find that the additional padding makes dressing and toileting more difficult and time consuming. Adaptive clothing might remedy that situation. Patient and/or caregiver acceptance and support is a critical factor since consistent compliance is needed to maximize effectiveness.

¹ Cook, A.S., Baldwin, M., Yak, N., Pollissar, L., & Gruber, W. (1997). Predicting the probability for falls in community dwelling older adults. *Physical Therapy*, 77(8), 812-819.

² Knox, R. (1998, Jan. 19). Falls don't have to happen. *Boston Globe*.

³ MacRae, P.G., Lacourse, M., & Moldavon, J. (1992). Physical performance measures that predict faller status in community dwelling older adults. *Journal of Orthopedic and Sports Physical Therapy*, 16(3), 123-128.

⁴ Koch, M., Schalk, M.G., Baker, D., Palumbo, S., & Tinetti, M. (1994). An impairment and disability assessment and treatment protocol for community living elderly persons. *Physical Therapy*, 74(4), 286-298.

⁵ Adler-Trainee, M. (1995, Sept. 8). Falls in the senior population. *Occupational Therapy Forum*, pp. 8-11.

⁶ Van Swearingen, J.M., Paschal, K.A., Bonino, P., & Yang. (1996). The modified gait abnormality rating scale for recognizing the risk of recurrent falls in community dwelling older adults. *Physical Therapy*, 76(9), 994-1001.

⁷ Sattin, R.W. (1992). Falls among older persons: A public health perspective. *Annual Review of Public Health*, 13, 489-508.

⁸ Baker, S.P., Ginsburg, M.J., & Giuhua, L. (1992). *The injury fact book*. New York: Oxford University Press.

⁹ Hoard, S. (1997, June). New technology can reduce falls. *Briefings on Assisted Living*, p.4.

¹⁰ Holliday, P.J., Cott, C.A., & Torresin, W.D. (1992). Preventing accidental falls by the elderly. In J. Rothman and R. Levine (Eds.), *Prevention practice: Strategies for physical therapy and occupational therapy* (pp. 234-257). Philadelphia: W.B. Saunders.

¹¹ Tinetti, M.G., Speechley, M., Ginter, S.F. (1988). Risk factors for falls among elderly persons living in the community. *New England Journal of Medicine*, 319, 1701-1707.

¹² Tideiksaar, R. (1998). *Falls in older persons*. Baltimore: Health Professions Press.

Additional Resource

Adams, R.C. (June 12, 1995). Multiple risk factor intervention successful. *ADVANCE for Occupational Therapy*, pp. 14-15.

Wolter, L.L. (1996). A clinical synthesis of falls intervention trials. *Topics in Geriatric Rehabilitation*, 11(3), 9-19.

George Gross, Tsan-Hui Chen and Carolyn Flaherty are part of the Elder Service Plan Administrative Staff at East Boston Neighborhood Health Center, East Boston, MA.

This study was not solicited by the manufacturer. The article was produced here with the cooperation of the manufacturer.

EXHIBIT 18

Interpretation of Biomechanical Testing of HipSaver® Dual-mechanism Shunting/Absorbing AirPad

August 2000

Background: HipSaver pads were tested at the Harvard affiliated laboratory in 1996 and found to offer 10% better impact attenuation than SafeHip® (SafeHip is the product resulting from the initial research efforts as reported in *The Lancet* 1993 341:11-18). Since then HipSaver has researched a variety of materials with various attributes for potential incorporation into the HipSaver product. In August 2000, the selected construction (HSPE4 12.7mm) was sent to the Tampere University of Technology Applied Mechanics Laboratory for impact testing on a mechanical hip system. The research group affiliated with this laboratory is currently most active in the development and biomechanical testing of hip protectors and has several published reports on the subject.

HipSaver Pad Construction: HipSaver encloses a 1/2" (12.7mm) thick damping foam material in a waterproof/air tight pouch. The pads taper down to 1mm at the edge. The pouch is either RF or heat sealed around the perimeter. Pad diameters are 6.5 to 7.5 inches. These pads are sewn into polycotton underwear so as to overlie the trochanters.

Test Results: The test system and protocol are identical to that reported in *Bone* 1999 Aug. 25(2):229-35 (abstract enclosed). The pad being tested is affixed to a surrogate hip bone and then impacted by a swinging pendulum. Load cells capture the amount of force on the system. The test report on HipSaver shows the HipSaver pad (HSPE4 12.7mm) lowered a typical falling force of 7200N to below the fracture threshold of 3100N +/- 1200N. The following table compares the results from the HipSaver test to other pads tested in the *Bone* report (using the identical system and protocol):

Pad Id.	Description	7200N Fall Force Reduced to
KPH2	35mm height, polyethylene shell	760N
SafeHip	25mm height, polypropylene shell	2240N
Saftpants	20mm thick, low density polyethylene (soft)	2270N
HipSaver HSPE4	12.7mm thick, urethane foam in pouch (soft)	1790N

Conclusion: Only KPH2 and HipSaver reduced the applied force clearly below the fracture threshold of 3100N (+/- 1200N). A lower value on this test indicates better protective capacity since the values represent force REDUCTION. The above shows HipSaver to offer 20% more attenuation than Safehip.

The Damping Foam Absorbs the Shock and the Displaced Air Redistributes the Forces in the AirPad:

Although the HipSaver pad has the lowest profile (thinness) and is the softest, it performed remarkably well when compared to the stiffer and thicker pads. This result stems from the fact that the airtight pouch renders an "energy shunting" or diverting effect on the applied force: the initial impact is absorbed by the urethane foam and the displaced air from the foam inflates or distends the surrounding pouch. Hence, much similar to automotive air bag, the force is redistributed over a larger and softer area. This inflation effect can be demonstrated by pushing a HipSaver pad with the heel of the hand and observing the distention of the pouch. The HipSaver pad is thus a dual mechanism "shunting/absorbing" air pad.


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Trochanteric pad tests HipSaver®

Two thicknesses of the hip protector type HSPE4 were tested. The thickness of the thinner model was 8.4 mm, the thicker one was 12.7 mm. These pads were enclosed in waterproof nylon and polycotton knit material. These pad tests were performed at the midrange force of 7230N as per the protocol and the testing system described in *Bone* 1999 Aug. 25(2):229-35. The above-mentioned force was attenuated by soft tissue to the value of 5600 N, which match the average peak hip impact force measured in the muscle-relaxed state during in vitro falling tests (Robinovitch et al. 1991). Pad named PE30 (thickness 20 mm) was used to simulate the soft tissue and that pad was changed after every impact for a new one. Six impact tests were done for every pad type. Then the force measurements were filtered and evaluations of averaged peak values and standard deviations were calculated to get the maximum compressive impact forces as seen in Table 1. Typical time-dependent test curves of both thicknesses are seen in Figure 2.

Table 1 Averaged trochanteric impact forces and their standard deviations.

Speed	Energy	HSPE4 8.4 mm		HSPE4 12.7 mm	
		Mean kN	Std kN	Mean kN	Std kN
1.9 m/s	74 Nm	2.51	0.071	1.79	0.067

Description of facilities and the calibration

The data acquisition system is based on Microstar Laboratories Data Acquisition Processor DAP 3200A. The DAP 3200A has the DPL operating system.

The acquired data were analyzed by Matlab, which is used to numeric computation and visualization. The Matlab is a trademark of Math Works.

The sampling time was 10 μ s. The number of acquired points was 1500 for each test curve. Known pads were used to see the same impact force level as reached in the tests earlier. The test system is seen in Figure 1.

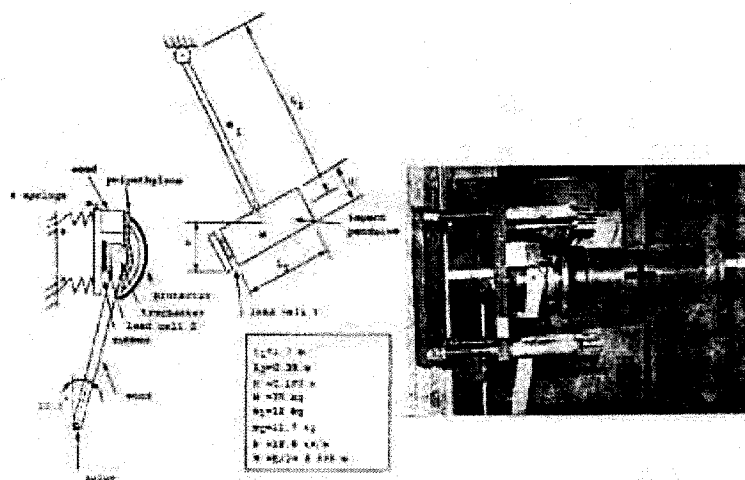


Figure 1 The hip protector testing system.

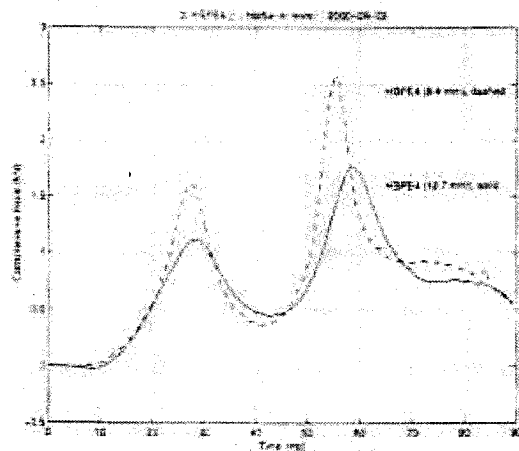


Figure 2 Test curves for the third impact of HSPE4 of the both thicknesses.

Tampere 2000-09-15

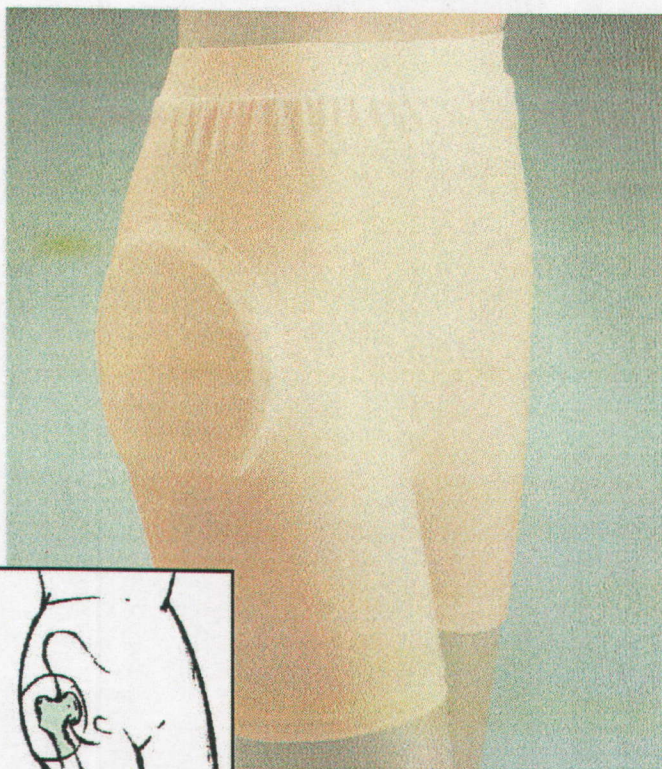
Jarmo Poutala, Laboratory Manager

Jarmo Poutala

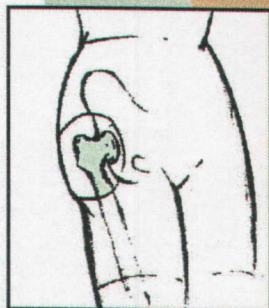
NEW!

Posey® Hipsters

A better way to protect your patients



#6016 Standard Unisex Brief



#6017 Incontinent Brief

*Posey Hipsters can be worn discreetly under clothing.*

- Soft foam pads help minimize potential damage that can occur from a fall.
- Low profile, 1/2" thick pads allow the Hipster to be virtually undetectable under clothing.
- Discreet low-profile pads with soft foam help improve patient compliance.
- **NO ASSEMBLY REQUIRED** – Completely launderable according to CDC standards for soiled linen **WITHOUT** removing the pads.
- 100% Latex Free
- Incontinent brief features a snap front for easier application over adult diapers. May also be worn as a male fly model.
- Available in five sizes to ensure proper fit.

Sizing Chart

Size	Waist Measurement	Hip Measurement
S	28" - 30"	35" - 37"
M	32" - 34"	39" - 41"
L	36" - 38"	43" - 45"
XL	40" - 42"	47" - 49"
XXL	44" - 48"	51" - 53"

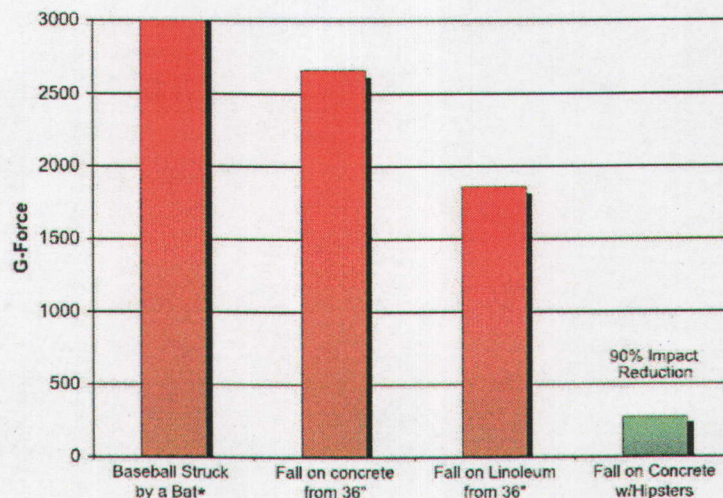
POSEY CA*Care Alternatives Division*

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PC 3006

Posey Hipsters Proven Effective in Laboratory Test

An independent laboratory study was conducted to determine the most effective impact absorbing material as of July 2001. A test was created that would simulate a fall causing direct impact to the greater trochanter. In this study, a weight was released in a guided drop to simulate a 120lb subject falling from a height of 36", or the estimated height of the hip above the floor for a typical nursing home resident. The baseline measurement of impact force was determined to be a fall directly onto concrete. The G-Force of a fall under this scenario was 2,660G's and, for purposes of comparison, is just slightly less impact force than that of a baseball being struck by a bat. In this extreme test, the low profile Posey Hipster reduced the impact force by 90% and showed excellent impact energy absorption.



Testing was conducted by Garwood Laboratories, July 2001. Data on file at J.T. Posey Company
*Source: www.madsci.org

Clinical References Supporting the Use of Hip Protectors

Title:
Author:
Publication:

External Hip Protectors to Prevent Osteoporotic Hip Fractures

A. Ekman, H. Mallmin, K. Michaëlsson, S. Ljunghall
The Lancet, volume 350, August 23, 1997

PC 3007

Study Objectives: Ekman and colleagues conducted a controlled study on the use of hip protection to prevent hip fractures. One expectation was to either confirm or disprove the Lauritzen and colleagues 1993 reported findings.

Results: The use of hip protectors as preventative treatment for hip fractures was validated. "Our study confirms a reduced risk for hip fractures of the same magnitude as the previous report."

Recommendations: "With improved compliance, external hip protectors should be an effective prophylactic against hip fractures."

Title:
Author:
Publication:

Prevention Of Hip Fracture in Elderly People

Pekka Kannus, M.D., Ph.D., et al
The New England Journal of Medicine, Vol. 343, No. 21, November 21, 2000

Study Objectives: The purpose of this study was "to determine whether an external hip protector would be effective in preventing hip fractures among elderly adults." The study population was comprised of elderly adults from 22 community based health-care centers in Finland; a treatment group of 653 and a control group of 1,148 participants.

Results: The degree of compliance with the hip protector was $48 \pm 29\%$. The hip protector group suffered 13 hip fractures, 9 of which occurred while not wearing the hip protector, compared to 67 hip fractures in the control group.

Recommendations: "We conclude that the risk of hip fractures can be reduced in frail elderly adults through the use of an anatomically designed external hip protector. Only 41 persons need to use the hip protector for one year (or 8 persons, for five years) in order for one fracture to be prevented."

EXHIBIT 20

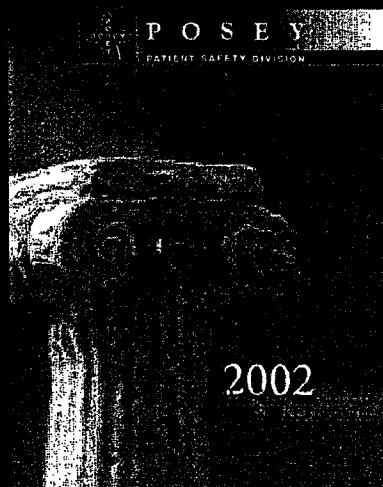
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Care Alternatives Division

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POSEY
PATIENT SAFETY DIVISION

PC 1031

POSEY CA

Alternatives in Care

FALL PREVENTION

POSEY HIPSTER III

Indications: Patients at risk for falling; those at risk for hip fracture.



#6016



#6017

Several studies have documented the efficacy of external hip protectors in preventing hip fractures. The Posey Hipster III features impact absorbing pads over the critical fracture area to help minimize potential damage, including hip fractures that can occur from a fall. The brief is made from comfortable poly-cotton-Lycra® with a low-profile pad positioned over each hip. These low profile pads are sewn into a slim fitting brief allowing the Hipster III to be discreetly worn under clothing. The one-piece design allows for easy home or institutional laundering.

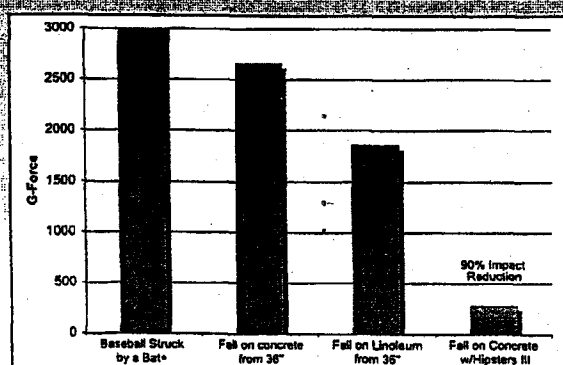
Hipster III is available in two styles; standard unisex and incontinent models. The standard unisex brief easily slips on over undergarments or can be worn as underwear. The incontinent brief features a snap front for easier application over adult diapers. The Hipster III fits comfortably around the patient's waist and features a latex-free elastic waistband. 47% polyester, 47% cotton, 6% Lycra. Latex-free.

CAT. #	STYLE	
6016	Hipsters III Standard Brief (Replaces Posey #6010 unisex Hipster brief)	
6017	Hipsters III Incontinent Brief (Replaces Posey #6011 Incontinent Hipster II brief)	
SIZE	WAIST SIZE	HIP SIZE
S	28-30"	35-37"
M	32-34"	39-41"
L	36-38"	43-45"
XL	40-42"	47-49"
XXL	44-46"	51-53"



Low Profile - Both styles fit discreetly under clothing.

Posey Hipsters Proven Effective in Laboratory Test



An independent laboratory study was conducted to determine the most effective commercially available impact absorbing material as of July 2001. A test was created that would simulate a fall causing direct impact to the greater trochanter. In this study, a weight was released in a guided drop to simulate a 120 lb. subject falling from a height of 36" or the estimated height of the hip above the floor for a typical nursing home resident. The baseline measurement of impact force was determined to be a fall directly onto concrete. The G-Force of a fall under this scenario was 2,660 G's and, for purposes of comparison, is just slightly less impact force than a baseball being struck by a bat*. In this extreme test, the low profile Posey Hipster III reduced the impact force by 90% and showed excellent impact energy absorption.

*Source: www.madsci.org.

1-800-44-POSEY

800-767-3933 fax

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PC 1032

EXHIBIT 21



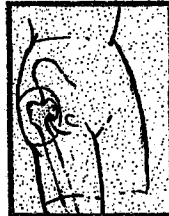
Posey® EZ On Hipsters™

In 1996, hospital admissions for hip fractures among people aged 65 and older totaled 340,000 and is expected to exceed 500,000 with a projected annual cost of \$240 billion by the year 2040.¹ Tragically, half of all older adults hospitalized for hip fractures cannot return home or live independently after their injury and about one quarter will die within one year due to the fracture or related complications.²

Several studies have documented the efficacy of external hip protectors in preventing hip fractures. These same studies also point out that patient compliance is a driving factor in product effectiveness. Posey Hipsters feature impact absorbing, soft foam pads over the critical fracture area to help minimize potential damage, including hip fractures that can occur from a fall. The low profile pads allow the Hipsters to be discreetly worn under clothing. These soft pads offer greater comfort when compared to hard shell style hip protectors. Patient comfort, coupled with the low profile design, helps increase patient compliance.

The EZ On Hipsters are applied around the waist and lower thigh using the hook-and-loop attachments, and allow the patients to wear their own undergarments. The mesh material is water permeable, allowing the EZ On Hipsters to be worn during bathing.

EZ On Hipsters feature removable pads. Although the pads are removable, the Hipsters can be laundered with the pads in place. Removing the pads prior to laundering will help prolong the life of the product.



While no product can provide complete protection from hip fractures, Posey Hipsters will help to minimize the potential for damage that can occur from a fall.

#6019 EZ On Hipsters

#6008 Replacement Pads, 1 pair

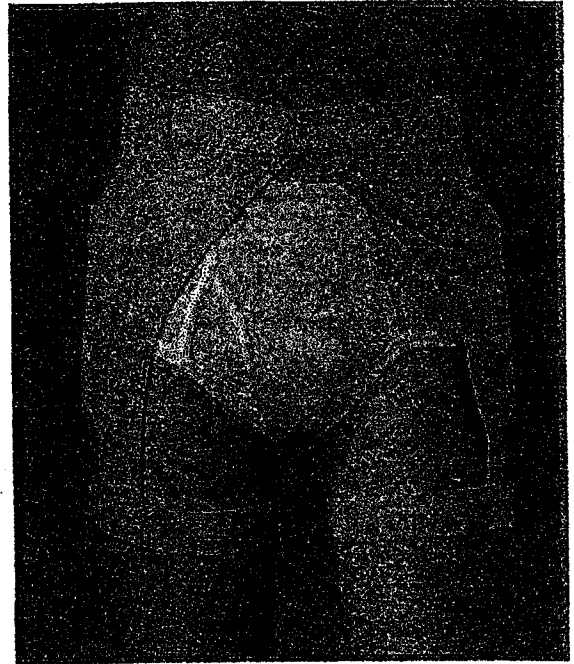
Application Instructions

1. Unfasten the hook and loop at the waist and thighs.
2. Wrap the garment around your waist. The labels should be oriented towards the back and on the inside of the waistband.
3. Fasten the hook and loop at the front of your waist. The waistband should be securely fastened to allow minimal shifting of the garment but should not feel tight or restrictive.
4. Pull the left panel taut over the left hip and thigh. The pad should be positioned directly over the hip joint.
5. Secure around the lower thigh using the hook and loop attachment. The elastic band should be tight enough to prevent the pad from sliding out of place without restricting circulation.
6. Repeat steps 4 and 5 on right side.

Laundering Instructions

Posey Hipsters may be washed according to CDC standards (see symbols below). Using the lower temperature washing and drying cycle for non-contaminated linen will prolong product life.

- If hook and loop does not adhere, it is most likely due to a collection of lint. Clean hook by brushing with a stiff brush.
- If pads are removed, wipe clean with mild, liquid disinfectant before replacing in the pants.



#6019

Sizing Chart		
Size	Waist Measurement	Hip Measurement
S	28" - 30"	35" - 37"
M	32" - 34"	39" - 41"
L	36" - 38"	43" - 45"
XL	40" - 42"	47" - 49"
XXL	44" - 48"	51" - 53"

⚠ WARNING

Due to the random possibilities of fall characteristics, the Posey Company makes no guarantee, express or implied, that the user is protected from hip trauma. The skin under the pants should be assessed regularly and Hipsters should be changed and washed after each incontinent episode to prevent skin breakdown.

⚠ WARNING

- Posey Hipsters contain foam pads that are sealed in a pouch to protect the foam.
- If the pouch is cut or the seal is broken in laundering, moisture will enter the pouch and compromise the impact absorption quality of the foam.
- Test pouch and foam integrity by squeezing the pad in one fist, forcing the air to one end, resulting in an air bubble.
- If you hear or feel air or liquid escaping, or the foam feels soft and spongy, the pouch is damaged.
- Remove the damaged pouch and replace with a new one.

¹ Centers for Disease Control and Prevention, 3 Aug 2001, www.cdc.gov. ² Rubenstein, Lawrence, M.D., M.P.H. (2000) Hip Protectors - A Breakthrough in Fracture Prevention. The New England Journal of Medicine.

J.T. Posey Company 5635 Peck Road • Arcadia, CA 91006-0020 USA • Tel: 800-447-6739 or 626-443-3143 • Fax: 800-767-3933 or 626-443-5014 • www.posey.com

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PC 2861

Clinical References Supporting the Use of Hip Protectors

Title: *External Hip Protectors to Prevent Osteoporotic Hip Fractures*
Author: A. Ekman, H. Mallmin, K. Michaëlsson, S. Ljunghall
Publication: The Lancet, volume 350, August 23, 1997

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Publication: The New England Journal of Medicine, Vol. 343, No. 21, November 21, 2000

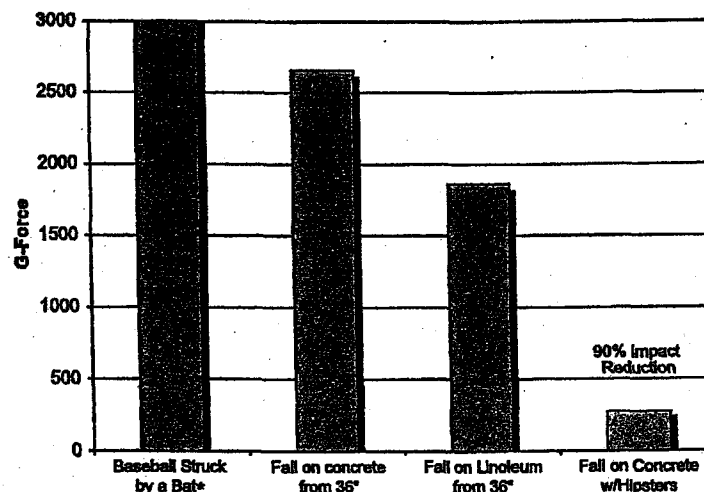
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Testing was conducted by Garwood Laboratories, July 2001. Data on file at J.T. Posey Company
 *Source: www.madsci.org

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PC 2862